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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

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14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,911

Applicant(s)

HARRISON ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 23-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This is a First Office Action on the Merits of the application filed February 16, 2001, which claims priority to U.S. Provisional application 60/183,573 filed February 18, 2000. This Office Action is a reply to the "Response Under 37 C.F.R. § 1.111 and 1.143 filed October 22, 2002 (Paper No. 13). Claims 1-29 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-22) in Paper No. 13 is acknowledged. The traversal is on the ground(s) that "[t]he implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct" (page 3, paragraph 2). Applicant submits that the groups are united by a principal feature, said principal feature being the concept that certain growth factors play an important role in promoting differentiation of pancreatic cells, and that the methods of groups I-IV are all different aspects a single invention. Applicant further argues that the reliance on the classification of the groups of claims does not establish independence and distinctness. Applicant states, "[t]he classification system is instead an aid in finding and searching for patents" (page 5, paragraph 1).

This is not found persuasive because Applicant's argument that groups united by a single concept must be examined together appears to confuse U.S. Restriction Practice with the rules for Unity of Invention under PCT Rule 13.1. Under 35 U.S.C. § 121, restriction is deemed proper if two or more "independent and distinct" inventions are claimed in one application, regardless of the existence of a unifying concept. With regard to Applicant's assertion that the inventions

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must be both independent and distinct, the M.P.E.P § 802.01 makes clear that dependent, or related, inventions may be properly divided if they are, in fact, “distinct” inventions, even though dependent. In the instant case, the inventions, though related conceptually, are distinct for the reasons provided in the restriction requirement (Paper No. 11).

Applicant’s point that the classification of groups should not be relied upon to establish independence and distinctness is taken. However, in the restriction requirement, the classification of groups is cited as evidence for the administrative burden of examining the claims together, not as evidence for independence or distinctness. For a proper requirement for restriction between patentably distinct inventions there must be a serious burden on the examiner if restriction is required. As stated by Applicant, the classification system is an aid in finding and searching patents. Clearly, examining inventions that fall in different classes or subclasses impose an additional burden of search, as each invention requires that a different class and subclass of patents be searched.

The requirement is still deemed proper and is therefore made FINAL.

In the remarks, Applicant expresses concerns regarding the impact of arbitrarily imposed restriction requirements on progress of science and the useful arts, filing costs and post issue litigation of patent rights. As these concerns are predicated on the arbitrary imposition of restriction requirements and the present restriction requirement is not arbitrarily imposed (for the reasons provided herein above), they are not germane to the instant case.

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Claims 23-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 13.

Drawings

The drawings are objected to for the reasons provided on the attached PTO-948. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

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Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Claim Objections

Claim 11 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim (i.e. claim 10). See MPEP § 608.01(n). In the interest of compact prosecution, the claim has been examined according to its full scope; however, appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry,

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whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

The claims of the instant application are directed to a method of stimulating or otherwise facilitating the formation of colonies of pancreatic cells containing insulin-secreting cells, said method comprising culturing the cells in the presence of a BMP, laminin-1, laminin-1-containing extracellular matrix or a functional derivative, homologue, mimetic, analogue or agonist of BMP, laminin-1 or laminin-1-containing extracellular matrix. The Guidelines for Written Description state "The claimed invention as a whole may not be adequately described if the claims require an essential or critical element which is not adequately described in the specification and which is not conventional in the art" (Column 3, page 71434). In the instant case, the molecules used in the method of stimulating or facilitating formation of colonies of mammalian pancreatic cells containing insulin-secreting cells are critical to the method. Therefore adequate written description of the method requires that Applicant adequately describe the molecules used.

In the first paragraph on page 14 of the specification, Applicant defines BMP to encompass "a polypeptide having BMP properties including the ability to stimulate or otherwise facilitate the formation of insulin-secreting cells". Therefore, BMP, as it is defined in the instant specification, encompasses any and all polypeptides having the functional characteristic of stimulating or otherwise facilitating the formation of insulin-secreting cells regardless of structure. Because laminin-1 is not defined in the specification, it is assumed to have the structural and functional properties of laminin-1 as they are known in the art; however, as the claims encompass mimetics, any molecule having the functional properties of laminin-1 is also

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encompassed by the claims. Therefore the molecules of the claims encompass a genus of any and all molecules capable of stimulating or otherwise facilitating formation of colonies of mammalian pancreatic cells containing insulin-secreting cells.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species, by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics (see MPEP 2163 (ii)). Applicants disclose a single species of laminin-1 that meets the functional limitations for the critical element of the claim. With regard to BMP, Applicants describe three species, BMP 6/6, BMP 7/7, and BMP 4/7, having the ability to stimulate or otherwise facilitate the formation of insulin-secreting cells only in the presence of laminin-1 (see example 12 beginning on page 36, especially the first sentence of the third full paragraph on page 36). These four species are clearly not representative of the widely divergent genus of any and all molecules having the ability to stimulate or otherwise facilitate the formation of insulin-secreting cells.

With regard to derivatives, homologues and analogues of the described species, applicant has provided a desired functional characteristic and general instructions on how polypeptide molecules can be modified (see especially pages 15-18). However, in order to describe the structure of a polypeptide in functionally relevant terms, Applicant must describe more than simply the primary amino acid sequence, as the functionality of a polypeptide is comprised within its higher order structure (i.e. secondary and tertiary structure). Because it is presently impossible to envision the higher order structure of a polypeptide based on a description of its primary structure alone, the skilled artisan would not recognize that Applicant was in possession of any and all derivatives, homologues and analogues of BMP or laminin-1 polypeptides having

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the function of stimulating or otherwise facilitating the formation of insulin-secreting cells based on a description of the primary structure of any and all derivatives, homologues and analogues of BMP or laminin-1 polypeptides.

As indicated in the Guidelines, a genus of polypeptides might also be adequately described by disclosure of structural characteristics coupled with correlation of those structural characteristics with functional properties of the polypeptide. In the instant case, the disclosure provides that laminin-1 stimulates or otherwise facilitates the formation of insulin-secreting cells and BMP 6/6, BMP 7/7, and BMP 4/7, have the ability to stimulate or otherwise facilitate the formation of insulin-secreting cells only in the presence of laminin-1. There is nothing in the disclosure, however, that would allow the skilled artisan to extend this knowledge beyond the disclosed species.

In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of *any* and *all* molecules capable of stimulating or otherwise facilitating the formation of insulin-secreting cells. Therefore, only the described species, (i.e. laminin-1, BMP 6/6, BMP 7/7, and BMP 4/7) meet the written description provision of 35 U.S.C. §112, first paragraph.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of stimulating or otherwise facilitating formation of colonies of mammalian pancreatic cells comprising culturing pancreatic cells in the presence of laminin-1 or in the presence of laminin-1 and BMP 6/6, BMP 7/7 and BMP 4/7, does not reasonably

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provide enablement for any method comprising culturing pancreatic cells in the absence of laminin-1, or in the presence of any and all functional derivatives, homologues, mimetics, analogues or agonists of BMP and laminin-1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

Nature of the invention: The instant invention provides methods of stimulating or otherwise facilitating formation of colonies of pancreatic cells containing insulin comprising culturing the pancreatic cells in the presence of BMP and/or laminin-1.

Breadth of the claims: As described herein above, the claims encompass a method wherein pancreatic cells are cultured in the presence of any and all molecules capable of stimulating or otherwise facilitating formation of colonies of pancreatic cells containing insulin either alone or in the presence of laminin-1. Therefore the claims are directed to a method of using a genus of molecules, which molecules are not distinguished by any structural feature.

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State and level of predictability in the art: The prior art, exemplified by Kerr-Conte *et al.* (1996) *Diabetes* 45:1108-1114, Jiang *et al.* (IDS #9), and Dudek (1990) U.S. Patent No. 4,935,000 (described in detail herein below), teaches that extracellular matrix and laminin-1 can facilitate formation of colonies of pancreatic cells containing insulin. However, these studies provide no examples of molecules other than laminin-1 that can facilitate formation of colonies of pancreatic cells containing insulin and provide no structure-function analysis of laminin-1 to guide the skilled artisan in the construction of functional derivatives of laminin-1. Therefore, the prior art provides no means by which the skilled artisan could predict which molecules encompassed by the instant claims would have the functional properties set forth.

Likewise, in an article published well after the effective filing date of the instant application, Jiang *et al.* (2002) *J. Cell Sci.* 115:753-760 teach that BMPs-4, -5 and -6 promote the formation of cystic colonies from pancreatic cells but provide no structure-function analysis that would enable the skilled artisan to construct functional derivatives of BMP without resorting to blind trial and error analysis of each and every possible derivative, analogue or homologue of BMP to identify the molecules encompassed by the claim. Furthermore, Jiang *et al.* explicitly teach that the BMPs tested did not facilitate formation of colonies of pancreatic cells containing insulin in the absence of laminin-1 (see especially the final paragraph on page 754). The relevant art therefore provides no guidance whatsoever to enable the skilled artisan to identify a BMP molecule capable of facilitating formation of colonies of pancreatic cells containing insulin in the absence of laminin-1.

The relevant art discloses only four species of molecules having the functional properties of the laminin-1, BMP and extracellular matrix, and functional derivatives, homologues

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mimetics and analogues or agonists thereof of the claims; and suggests no attributes that would be common to any and all molecules capable of facilitating formation of colonies of pancreatic cells containing insulin. Therefore the skilled artisan is dependent upon the teachings of the instant disclosure to provide sufficient guidance to use the invention commensurate with the full scope of the claims without engaging in undue experimentation.

Amount of direction provided by the inventor and existence of working examples: The disclosure provides that laminin-1 and BMP 6/6, BMP 7/7 and BMP 4/7, in the presence of laminin-1, stimulate pancreas cells to form insulin positive colonies. On pages 15-18, the disclosure further provides a description of various ways that proteins can be modified and the “Examples” provide assays for formation of colonies containing insulin-secreting cells. However, the disclosure provides no guidance that would enable the skilled artisan to identify the molecules used in the claimed method short of blind trial and error experimentation. In contrast, the instant disclosure teaches that molecules such as BMP 4/4 and BMP 4/6 do not have the same activity as BMP 6/6, BMP 7/7 and BMP 4/7 despite their closely related structure. Given this teaching, the skilled artisan would not predict that even closely related molecules would be functional in the claimed method.

Relative skill of those in the art and quantity of experimentation needed to make or use the invention: Although the skill in the relevant art is high, given the breadth of claims, which encompass a method of using any and all molecules capable of facilitating formation of colonies of mammalian pancreatic cells containing insulin-secreting cells, and the absence of teachings from the prior art and disclosure that would enable the skilled artisan to identify the molecules used in the method, the skilled artisan would not be able to practice the claimed invention

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commensurate with the full scope of the claims without first resorting to undue experimentation to identify the molecules to be used in the method. When considering the amount of experimentation necessary, it is important to keep in mind that there is no structural limitation placed on the molecules used and no guidance provided that would allow the skilled artisan to quickly arrive at a reasonable number of candidate molecules. The skilled artisan would therefore have to resort to trial and error experimentation to identify from an almost infinite number of candidate molecules each and every molecule encompassed by the claim. This burden of experimentation would clearly be undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is indefinite in its recitation of “culturing pancreatic cells in the presence of one or both of a bone morphogenetic protein (BMP) or a functional derivative...” It is unclear whether Applicant intends that the claim be directed to a method wherein BMP is provided in combination with a derivative, homologue, etc. It seems that the phrase “or both” is a typographical error and removing the phrase would obviate this rejection. Otherwise, applicant should provide clarification.

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6, 7, 10 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Jiang *et al.* (1999) *Diabetes* 48:722-730 (IDS #9).

The claims 1, 6 and 7 are directed to a method of stimulating or otherwise facilitating formation of colonies of mammalian pancreatic cells containing insulin-secreting cells, said method comprising culturing pancreatic cells in the presence of laminin-1 or laminin-1-containing ECM for a time and under conditions sufficient for colonies to form comprising insulin secreting cells.

Jiang *et al.* teaches a method of stimulating or otherwise facilitating formation of colonies of mammalian pancreatic cells containing insulin-secreting cells, said method comprising culturing pancreatic cells in the presence of laminin-1 for a time and under conditions sufficient for colonies to form comprising insulin secreting cells (see especially “**Pancreatic cell cultures**” and “**ECM proteins**” beginning the second column on page 723 and continued through the first paragraph on page 724, and Figure 3 and the caption thereto).

Claims 4 and 10 further limit the methods of claims 1, 6 and 7 to a method wherein laminin-1 is provided at a concentration of from about 1 µg/ml to about 1000 µg/ml.

Jiang *et al.* teaches a method wherein laminin-1 is provided at a concentration of 200 µg/ml (see especially the caption to Figure 3).

Claim 11 is further limited by the methods of claims 1, 4, 6, 7 and 10 to a method wherein the pancreatic cells are pancreatic lineage embryonic stem cells.

Jiang *et al.* teaches a method wherein the pancreatic cells are pancreatic lineage embryonic stem cells (see especially the first paragraph on page 723).

The method and cells taught by Jiang *et al.* are the same as those taught in the instant application; therefore, the limitations of the claims are met by Jiang *et al.*

Claims 1, 6, 7, 12 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by either one of Kerr-Conte *et al.* (1996) *Diabetes* 1108-1114 or Dudek (1990) U.S. Patent No. 4,935,000.

The limitations of claims 1, 6 and 7 are set forth herein above. Claims 12 and 17 are directed to a method of stimulating or otherwise facilitating formation of cystic epithelial colonies according to the methods of claims 1, 6 and 7.

Kerr-Conte *et al.* teaches a method of stimulating or otherwise facilitating formation of colonies of mammalian pancreatic cells containing insulin-secreting cells, said method comprising culturing pancreatic cells in the presence of laminin-1-containing ECM for a time and under conditions sufficient for colonies to form comprising insulin secreting cells (see especially the first full paragraph on page 1109, the second paragraph on page 1113 and Table 4 and the caption thereto). Further, Kerr-Conte *et al.* teaches a method wherein the colonies of pancreatic cells containing insulin secreting cells are cystic colonies (see especially the paragraph bridging columns 1 and 2 on page 1112).

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Dudek teaches a method of stimulating or otherwise facilitating formation of colonies of mammalian pancreatic cells containing insulin-secreting cells, said method comprising culturing pancreatic cells in the presence of laminin-1-containing ECM for a time and under conditions sufficient for colonies to form comprising insulin secreting cells (see especially "Example 1" bridging columns 5 and 6). Further, Kerr-Conte *et al.* teaches a method wherein the colonies of pancreatic cells containing insulin-secreting cells are cystic colonies (see especially the third full paragraph in column 6).

The methods taught by Kerr-Conte *et al.* and Dudek are the same as the methods taught in the instant application; therefore the claims are anticipated by the prior art.

Conclusion

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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December 3, 2002



JAMES KETTER
PRIMARY EXAMINER